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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/671,005      | 09/25/2003  | Andrzej Fertala      | 003252-53201        | 4536             |

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EXAMINER

KOSSON, ROSANNE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/671,005             | FERTALA, ANDRZEJ    |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Rosanne Kosson         | 1651                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on January 22, 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 2, drawn to a recombinant collagen-like protein comprising 1-5 tandem repeats of a collagen domain, wherein the collagen domain is D1, D2, D3, D4 or D5, classified in class 530, subclass 356.
- II. Claim 3, drawn to a recombinant collagen-like protein having the structure CtD5D4D4D4D1Nt, classified in class 530, subclass 356.
- III. Claims 4-6, drawn to a recombinant nucleic acid molecule encoding a collagen-like protein comprising 1-5 tandem repeats of a collagen domain, wherein the collagen domain is D1, D2, D3, D4 or D5, and a host cell comprising the nucleic acid molecule, classified in class 536, subclass 23.5.
- IV. Claims 4-6, drawn to a recombinant nucleic acid molecule encoding a collagen-like protein having the structure CtD5D4D4D4D1Nt, and a host cell comprising the nucleic acid molecule, classified in class 536, subclass 23.5.

The inventions are distinct, each from the other because of the following reasons.

The protein of Group I is not related to the protein of Group II, as the protein of Group I has only one type of domain (D1 or D2 or D3 or D4 or D5), and this domain is present as a tandem repeat, i.e., an even number of times. The protein of Group I need

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not contain D1 or D4 or D5. The protein of Group II contains an odd number of collagen domains, and they are present an odd number of times. Therefore, these inventions are patentably distinct.

The protein of Group I is related to the nucleic acid molecule of Group III by virtue of the fact that the nucleic acid molecule codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, as the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as by chemical synthesis. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, these inventions are patentably distinct.

The protein of Group I is not related to the nucleic acid molecule of Group IV, as this nucleic acid molecule encodes a different protein, one that differs in structure and function. Therefore, these inventions are patentably distinct.

The protein of Group II is not related to the nucleic acid molecule of Group III, as this nucleic acid molecule encodes a different protein, one that differs in structure and function. Therefore, these inventions are patentably distinct.

The protein of Group II is related to the nucleic acid molecule of Group IV by virtue of the fact that the nucleic acid molecule codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, as the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made

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by other and materially distinct processes, such by chemical synthesis. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, these inventions are patentably distinct.

The nucleic acid molecule of Group III is not related to the nucleic acid molecule of Group IV, as each nucleic acid molecule encodes a different protein. The nucleic acid molecule of Group III encodes a protein that has only one type of domain (D1 or D2 or D3 or D4 or D5), and this domain is present as a tandem repeat, i.e., an even number of times. This protein need not contain D1 or D4 or D5. The nucleic acid molecule of Group IV encodes a protein that contains an odd number of collagen domains, and they are present an odd number of times. Therefore, these inventions are patentably distinct.

Additionally, the search for any one group is not required for any other group, thereby creating an undue burden of search and examination. Burden lies not only in the search of U.S. patents, but in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Further, the different groups have each acquired a separate status in the art, as shown in part by their different classifications. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

**Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

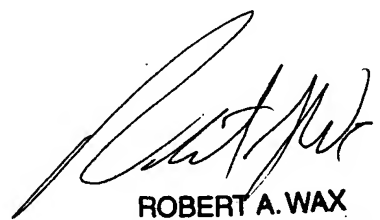
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner  
Art Unit 1651

rk  
2005-05-19



ROBERT A. WAX  
PRIMARY EXAMINER  
*Art Unit 1653*